IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABRAXIS BIOSCIENCE, LLC and CELGENE CORPORATION, Plaintiffs, v. HBT LABS, INC., Defendant.	C.A. No. 1:18-cv-2019-RGA **REDACTED - PUBLIC VERSION**

DEFENDANT HBT LABS, INC.'S OPENING BRIEF IN SUPPORT OF ITS MOTION TO DISMISS AND TRANSFER

Date: February 11, 2019

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I. INTRODUCTION

This is a Hatch-Waxman case concerning Defendant HBT Labs, Inc. ("HBT") proposed therapeutically equivalent (*i.e.*, generic) version ("HBT's NDA Product") of paclitaxel protein-bound particles for injectable suspension, currently marketed under the brand name ABRAXANE®. (Am. Comp., D.I. 6 ¶ 1.) FDA has approved ABRAXANE® to treat certain forms of cancer. (*Id.* ¶ 22.) Plaintiffs Abraxis BioScience, LLC ("Abraxis") and Celgene Corporation ("Celgene") (collectively, "Plaintiffs") bring the present action against HBT in an attempt to enforce all 12 patents listed in the Orange Book in reference to ABRAXANE®. (*Id.* ¶ 1.)

HBT hereby moves to dismiss and transfer. Specifically, HBT moves to dismiss Plaintiff Celgene from this action because it does not own, or otherwise have an enforceable interest in, the Patents-in-Suit, and thus lacks standing to assert such patents against HBT. HBT also moves under 28 U.S.C. § 1404(a) to transfer this action to the Central District of California because both HBT and Abraxis are located there and all substantive work regarding the Patents-in-Suit and HBT's NDA Product occurred there. Lastly, HBT moves to dismiss Counts I, IV, VI, VII, and IX-XII of the Amended Complaint (D.I. 6) on the grounds that the patents asserted in those claims only cover indications for which HBT has not sought FDA approval in its New Drug Application ("NDA").

II. FACTUAL AND PROCEDURAL BACKGROUND

HBT submitted NDA No. 211875[1] seeking FDA approval to market a generic version of ABRAXANE® prior to the expiration of the patents listed in the *Approved Drug Products with*

[1] Although HBT filed a New Drug Application, it nonetheless seeks approval pursuant to Section 505(b)(2) of the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(b)(2), to market a therapeutically equivalent version of a drug product previously approved by FDA. Thus, while HBT filed an NDA, many of the statutory provisions addressed herein are analogous to provisions applicable to an Abbreviated New Drug Application ("ANDA"). HBT's NDA Product will be referred to herein as "generic" for ease of reference.

Therapeutic Equivalence in reference to ABRAXANE® (collectively, the "Patents-in-Suit"). HBT certified to FDA pursuant to 21 U.S.C. § 355(b)(2)(A)(iv) that the claims of the Patents-in-Suit are invalid, unenforceable, and will not be infringed by the activities described in HBT's NDA. HBT also certified to FDA pursuant to 21 U.S.C. § 355(b)(2)(B) that it does not seek approval for the use of its NDA Product to treat pancreatic or lung cancer. On November 6, 2018, HBT notified Plaintiff Abraxis pursuant to § 355(b)(3) of both its Paragraph IV and method of use certifications to FDA. (Gerasimow Decl., Ex. A.) HBT notified Plaintiff Abraxis because it is, according to FDA, the holder of the NDA for ABRAXANE®. (*Id.*, Ex. W.)

On December 17, 2018, Plaintiffs Abraxis and Celgene filed suit against HBT in the District of New Jersey alleging infringement of the Patent-in-Suit (the "New Jersey Action"). (*See* C.A. No. 2:18-cv-17304-JMV-MF.) Plaintiffs served process in the New Jersey Action the next day, December 18, 2018. One day later, on December 19, 2018, Plaintiffs filed this action with the exact same claims as the New Jersey Action. (Compl., D.I. 1.) Because HBT lacks any connections to New Jersey, HBT asked Plaintiffs to dismiss the New Jersey Action. After initially refusing to do so, Plaintiffs voluntarily dismissed the New Jersey Action pursuant to Federal Rule of Civil Procedure 41(a)(1)(A)(i) on February 5, 2019 (Gerasimow Decl., Ex. B), just days before HBT would have moved to dismiss that action. On the same day, Plaintiffs filed an Amended Complaint (D.I. 6) in this Action with a single amendment purporting to update Plaintiff Abraxis' headquarters from Los Angeles, California to Summit, New Jersey (*id.* ¶ 3).

In their Amended Complaint (D.I. 6), Plaintiffs allege that HBT's submission of its NDA constituted an act of artificial patent infringement under 35 U.S.C. § 271(e)(2)(A), and that, upon FDA approval, HBT will allegedly infringe the Patents-in-Suit directly and indirectly under 35 U.S.C. § 271(a)-(c). (Am. Compl., D.I. 6 ¶¶ 25-27.) Plaintiffs allege infringement of the twelve

Patents-in-Suit in twelve separate counts, as follows: United States Patent Nos. 7,758,891 ("'891 patent," Count I); 7,820,788 ("'788 patent," Count II), 7,923,536 ("'536 patent," Count III), 8,034,375 ("'375 patent," Count IV), 8,138,229 ("'229 patent," Count V), 8,268,348 ("'348 patent," Count VI), 8,314,156 ("'156 patent," Count VII), 8,853,260 ("'260 patent," Count VIII), 9,101,543 ("'543 patent," Count IX), 9,393,318 ("'318 patent," Count X), 9,511,046 ("'046 patent," Count XI), and 9,597,409 ("'409 patent," Count XII) (collectively, "the Patents-in-Suit"). This Motion follows.

III. ARGUMENT

A. The Court Should Dismiss Plaintiff Celgene Because It Does Own, and Thus Lacks Standing to Enforce, Any of the Patents-in-Suit.

HBT first moves the Court to dismiss Plaintiff Celgene for lack of standing and, thus, for lack of subject matter jurisdiction pursuant to Federal Rule of Civil Procedure 12(b)(1). According to the Amended Complaint, Plaintiff Abraxis owns the Patents-in-Suit. (Am. Compl., D.I. 6 ¶¶ 1, 10-22.) At the same time, Plaintiffs never allege in the Amended Complaint that Celgene holds any rights in them whatsoever. Celgene is not ever alleged to be a licensee of the Patents-in-Suit. Without any such rights, Celgene has no standing and must be dismissed.

"Standing is a constitutional requirement pursuant to Article III and it is a threshold jurisdictional issue" properly addressed on a Rule 12 motion. *Abraxis BioScience Inc. v. Navinta LLC*, 625 F.3d 1359, 1363 (Fed. Cir. 2010); *see also Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992); *Ballentine v. United States*, 486 F.3d 806, 810 (3d Cir. 2007); *Pfizer Inc. v. Elan Pharm. Research Corp.*, 812 F.Supp. 1352, 1357 n.6 (D. Del. 1993) (concluding that a motion to dismiss for lack of patent ownership may be brought under Rule 12(b)(1) or 12(b)(6)).

Only the patentee and any exclusive licensee have standing to enforce a patent. *IpVenture Inc. v. Prostar Computer Inc.*, 503 F.3d 1324, 1325 (Fed. Cir. 2007) ("Only the entity or entities

that own or control all substantial rights in a patent can enforce rights controlled by that patent."); *see also Mars Inc. v. Coin Acceptors, Inc.*, 527 F.3d 1359, 1367 (Fed. Cir. 2008) (*mandate recalled on other grounds*) ("Only a patent owner or an exclusive licensee can have constitutional standing to bring an infringement suit."). Plaintiffs bear the burden of alleging facts sufficient to establish standing. *Sicom Sys. Ltd. v. Agilent Techs. Inc.*, 427 F.3d 971, 976 (Fed. Cir. 2005). To meet their burden, Plaintiffs must establish that, at the time the lawsuit was filed, they held enforceable title to the Patents-in-Suit. *Paradise Creations Inc. v. UV Sales Inc.*, 315 F.3d 1304, 1309 (Fed. Cir. 2003).

Here, Plaintiffs repeatedly allege that Abraxis owns the Patents-in-Suit without ever alleging that Celgene also holds some enforceable rights in them. For instance, in the very first paragraph of the Amended Complaint, Plaintiffs list the Patents-in-Suit and allege that they are "all owned by Abraxis." (Am. Compl., D.I. 6 ¶ 1.) Plaintiffs later allege that each of "[t]he [Patents-in-Suit] is assigned to Abraxis." (*Id.* ¶¶ 10-21.) Plaintiffs then allege that "Abraxis owns the patents-in-suit." (*Id.* ¶ 22.) At the same time, Plaintiffs allege no interest in the Patents-in-Suit held by Celgene. Thus, Plaintiffs have alleged no facts supporting Celgene's standing to enforce the Patents-in-Suit, and Celgene must be dismissed from the case. *Mars*, 527 F.3d at 1367; *see also Morrow v. Microsoft Corp.*, 499 F.3d 1332, 1340-41 (Fed. Cir. 2007).

While Plaintiffs allege that Abraxis is a wholly-owned subsidiary of Celgene (Am. Compl., D.I. 6 ¶ 3), and that Celgene holds the NDA for ABRAXANE® (*id.* ¶ 22), neither interest is sufficient to confer standing in this case. First, regarding Plaintiffs' alleged corporate relationship, the Federal Circuit has held that a parent corporation does not have standing to assert infringement of a patent owned by its subsidiary. *Sealant Sys. Int'l, Inc. v. TEK Global, S.R.L.*, 616 F. App'x 987, *990 (Fed. Cir. 2015); *see also Dole Food Co. v. Patrickson*, 538 U.S.

468, 475 (2003) ("A corporate parent which owns the shares of a subsidiary does not, for that reason alone, own or have legal title to the assets of the subsidiary.").

Second, as for Celgene's alleged ownership of the ABRAXANE® NDA, it is both demonstrably untrue and irrelevant in any event. In order to provide notice of its NDA to the holder of the ABRAXANE® NDA, HBT (through counsel) contacted FDA to request "the name and address of the NDA holder … for NDA 021660 (ABRAXANE®)." (Gerasimow Decl., Ex. C.) FDA responded that the NDA holder is "Abraxis Bioscience LLC."[2] (*Id.*) Thus, according to FDA, Celgene is not even the NDA holder, as alleged in the Amended Complaint. *Gould Elecs., Inc. v. United States*, 220 F.3d 169, 176 (3d Cir. 2000) ("In reviewing a factual attack [on subject matter jurisdiction], the court may consider evidence outside the pleadings.").

Even if, as Plaintiffs allege, Celgene holds the NDA to ABRAXANE® (Am. Compl., D.I. 6 ¶ 22), that is insufficient to confer standing on Celgene. Courts in this District have held that NDA holders do not have standing to bring suit under patents listed in the Orange Book:

> AstraZeneca LP [the original NDA holder] urges the Court to expand the second category of recognized plaintiffs [exclusive licensees] to include NDA holders and their authorized agents. However, the Court is not persuaded that a valid legal basis exists for this expansion…. [T]he Court does not understand the Hatch-Waxman Act or its amendments to have expanded the traditional categories of recognized standing in patent infringement actions, except to create a case or controversy by a defined act of infringement.

In re Rosuvastatin, 719 F. Supp. 2d 388, 399 (D. Del. 2010), *aff'd on other grounds*, 703 F.3d 511 (Fed. Cir. 2012). Thus, Celgene, which is not alleged to have any interest in the Patents-in-Suit, must be dismissed from this action for lack of standing to enforce the Patents-in-Suit. It does not matter whether it owns Abraxis, the alleged owner, or the ABRAXANE® NDA.

[2] In responding to the request of HBT's counsel, FDA also stated that Plaintiff Abraxis is located in Los Angeles. (Gerasimow Decl., Ex. C.) As discussed below in Pt. III.B.2.a.iv, that Abraxis is located in the Central District of California supports transfer of this action to that District.

B. The Court Should Transfer this Action to the Central District of California as a Much More Convenient Forum for Resolving the Parties' Dispute.

For the convenience of parties and witnesses, the Court should transfer this action pursuant to 28 U.S.C. § 1404(a) to the Central District of California, where both HBT and Abraxis are headquartered. The law of the regional circuit applies when considering a transfer motion. *In re TS Tech USA Corp.*, 551 F.3d 1315, 1319 (Fed. Cir. 2008). According to the Third Circuit, Section 1404(a) "was intended to vest district courts with broad discretion to determine, on an individualized, case-by-case basis, whether convenience and fairness considerations weigh in favor of transfer." *Jumara v. State Farm Ins.* Co., 55 F.3d 873, 883 (3d Cir. 1995). In particular, Section 1404(a) sets forth a two-step transfer analysis. In the first step, the court asks whether the action could have been brought in the proposed transferee venue and then, in the second step, determines whether transfer to that venue would best serve the interests of justice and convenience. *Mitek Sys., Inc. v. United Servs. Auto. Ass'n*, Civil Action No. 12-462-GMS, 2012 WL 3777423, at *4 (D. Del. Aug. 30, 2012). The Third Circuit has observed that, in analyzing the interests of justice and convenience, "there is no definitive formula or list of ... factors to consider." *Jumara*, 55 F.3d at 879. Instead, courts must analyze "all relevant factors" to determine whether "the litigation would more conveniently proceed and the interests of justice be better served by transfer to a different forum." *Id.* Nevertheless, in *Jumara*, the Third Circuit identified a set of private interest and public interest factors that should be considered. *Id.* at 879-80. As discussed below, these factors strongly favor transfer to the Central District of California.

1. This Action Could Have Been Brought in the Central District of California.

Here, the first step in the transfer analysis is satisfied. Section 1404(a) provides that an action may be transferred to "any other district or division where it might have been brought." 28 U.S.C. § 1404(a). An action "might have been brought" in any court that "(1) would have been a

proper venue and (2) would have had personal jurisdiction over the defendant had the case been filed there initially." Wright & Miller, FEDERAL PRACTICE AND PROCEDURE § 3841 (4th ed. 2014) (citing *Hoffman v. Blaski*, 363 U.S. 335 (1960)). Here, the Central District of California would have had personal jurisdiction over HBT, and would have been a proper venue.

Had Plaintiffs brought their claims in the Central District of California, that court would have had personal jurisdiction over HBT because HBT has been headquartered in Brea, California since its founding. (Hodgson Decl. ¶ 5; Am. Compl., D.I. 6 ¶ 4.) The city of Brea is in Orange County, which is encompassed by the Central District of California. Accordingly, courts in that district would have had personal jurisdiction over HBT. *Daimler AG v. Bauman*, 571 U.S. 117, 137 (2014) ("With respect to a corporation, the place of incorporation and principal place of business are paradig[m] ... bases for general jurisdiction.") (internal quotation omitted).

Venue would have been proper in the Central District of California as well. The patent venue statute, 28 U.S.C. § 1400(b), provides:

> Any civil action for patent infringement may be brought in the judicial district [1] where the defendant resides, or [2] where the defendant has committed acts of infringement and has a regular and established place of business.

Here, venue would have been proper in the Central District of California under the second prong of Section 1400(b). HBT's principal (and only) place of business is in Brea, California. (Hodgson Decl. ¶ 5; Am. Compl., D.I. 6 ¶ 4.) Further, HBT performed in Brea [redacted] each of the acts of infringement alleged in the Amended Complaint. (*See, e.g.*, Am. Compl., D.I. 6 ¶¶ 29, 31-33.) HBT planned, formulated, and prepared the samples of its NDA Product at its Brea facilities. (Hodgson Decl. ¶ 10.) HBT prepared its NDA there, too. (*Id.* ¶ 9.) [redacted] (*Id.* ¶ 12.) Thus, venue would have been proper in the Central District of California.

2. The *Jumara* Factors Strongly Favor Transfer to the Central District of California.

The Central District of California, being a proper venue, is also the most convenient and appropriate venue based on a balancing of both the private and public *Jumara* factors.

a. The Private Interest Factors Strongly Favor Transfer.

i. Plaintiffs Do Not Prefer Delaware as They Filed Suit First in New Jersey, and Have Nothing in Delaware.

This lawsuit presents the unusual case where the first private interest factor—the "plaintiff's forum preference as manifested in the original choice"—actually favors transfer. When analyzing this factor, the court should not consider simply the fact of the plaintiff's choice, but the reasons behind it. *Pragmatus AV, LLC v. Yahoo! Inc.*, C.A. No. 11-902-LPS-CJB, 2012 WL 4889438, at *4 & n.5 (D. Del. Oct. 15, 2012), *R&R adopted*, 2013 WL 174499 (D. Del. Jan. 16, 2013). Here, Plaintiffs' original choice of venue was the District of New Jersey, not this District. Plaintiffs brought this action only ***after*** filing and serving process in the New Jersey Action. Plaintiffs apparently choose to file this duplicative lawsuit merely to protect against the very real risk that the New Jersey Action would be dismissed for lack of personal jurisdiction and venue (which Plaintiffs later recognized in any event by voluntarily dismissing that action). (Gerasimow Decl., Ex. B.) Given that Plaintiffs would prefer to litigate elsewhere, this factor weighs in favor of transfer out of this District.

Indeed, Plaintiffs' preference for litigating elsewhere apparently stems from the fact that Plaintiff Celgene, the parent company of Plaintiff Abraxis, claims a principal place of business in New Jersey. (Am. Compl., D.I. 6 ¶ 2.) But Celgene is a not a proper party to this case, and its preference and convenience are thus irrelevant. As for Abraxis, Plaintiffs do not allege it has any facilities, employees, or operations in Delaware, which further reduces the weight afforded to their choice of forum, as the Federal Circuit, applying Third Circuit law, has so held. *In re*

Link_A_Media Devices Corp., 662 F.3d 1221, 1223 (Fed. Cir. 2011) (observing that a forum is not inherently more convenient for a plaintiff who has no contacts there); *see also Wacoh Co. Kionix Inc.*, 845 F. Supp. 2d 597, 601 (D. Del. 2012) (observing that the plaintiff's choice does not weigh "as strongly [in its favor] as it would if the plaintiff had its principal place of business (or, indeed, any place of business) in Delaware)").

ii. HBT Strongly Prefers the Central District of California.

This factor strongly favors transfer, as HBT much prefers to resolve this dispute in its home district, the Central District of California. (Hodgson Decl. ¶ 16.) All of HBT's facilities, personnel, records, and assets are located in Brea, California. (*Id.* ¶¶ 6-7.) By contrast, HBT has no offices, employees, or records in Delaware. (*Id.*) Accordingly, this factor weighs in favor of transfer to the Central District of California. *Nalco Co. v. AP Tech Grp. Inc.*, C.A. No. 13-cv-1063-LPS, 2014 WL 3909114, at *1 (D. Del. Aug. 8, 2014). That HBT chose to incorporate in Delaware does not affect the importance of its venue preference in the transfer analysis. *Id.*

iii. Any Alleged Actual Infringement Will Take Place in Brea, California.

The third private interest factor strongly favors transfer as well. As to this factor, which asks "whether the claim arose elsewhere," courts focus on the location of the design and production of the accused products. *McRo, Inc. v. Activision Blizzard, Inc.*, C.A. No. 12-cv-1508-LPS-CJB, 2013 WL 6571618, at *5 (D. Del. Dec. 13, 2013); *In re Hoffman-La Roche, Inc.*, 587 F.3d 1333, 1338 (Fed. Cir. 2009) ("[s]ignificant connections between a particular venue and the events that gave rise to a suit … should be weighed in that venue's favor.").

In this case, HBT planned, formulated, and prepared the samples of its NDA Product at its Brea, California facilities. (Hodgson Decl. ¶ 10.) HBT prepared its NDA there, too. (*Id.* ¶ 9.) Accordingly, all HBT personnel and documents relating to these activities are located there. (*Id.*)

[redacted]. (*Id.* ¶ 12.) [redacted] (*Id.*) [redacted] HBT presently has no plans of selling its NDA Product directly to entities located in Delaware. (*Id.* ¶ 15.) At most, Plaintiffs can only speculate that a small and indeterminate amount of HBT's NDA Product may end up in Delaware through indirect sales.

iv. The Parties' Convenience Strongly Favors the Central District of California.

The next private interest factor—"the convenience of the parties as indicated by their relative physical and financial condition"—strongly favors transfer. In assessing this factor, courts have traditionally examined a number of issues, including: "(1) the parties' physical location; (2) the associated logistical and operational costs to the parties' employees in traveling to Delaware (as opposed to the proposed transferee district) for litigation purposes; and (3) the relative ability of each party to bear these costs in light of its size and financial wherewithal." *Audatex N. Am., Inc. v. Mitchell Int'l, Inc.*, C.A. No. 12-cv-139 (GMS), 2013 WL 3293611, at *4 (D. Del. June 28, 2013) (internal quotations and citations omitted); *Abbott Labs. v. Roxane Labs., Inc.*, No. 12-457-RGA-CJB, 2013 WL 2322770, at *20-21 (D. Del. May 28, 2013) (same).

All of these issues favor transfer. Regarding the parties' physical location, HBT is physically located in the Central District of California, as discussed above. So too is the only plaintiff properly named in this case, Abraxis.[3] According to Plaintiffs' original Complaint, Abraxis' principal place of business is in Los Angeles, California.[4] (Compl., D.I. 1 ¶ 3.) Thus,

[3] As discussed above, Plaintiff Celgene is not a proper party to this Action.

[4] Although Plaintiffs amended their complaint in an effort to withdraw their admission that Abraxis is headquartered in Los Angeles, their earlier allegation nonetheless remains evidence of the location of Abraxis' headquarters. Wright & Miller, FEDERAL PRACTICE AND PROCEDURE § 2264 (3d ed. 2010) ("The general rule with regard to a pleading that has been withdrawn is that it

both parties in this case are located in the Central District of California, and this issue thus favors transfer to that venue. And for much the same reasons, logistical considerations strongly favor transfer. HBT is located fewer than 15 miles from the U.S. Courthouse for the Central District of California, Southern Division. (Gerasimow Decl. Ex. D.) Abraxis is similarly located fewer than 15 miles from the U.S. Courthouse for that District's Western Division. (*Id.*, Ex. E.) No matter which Division this action is transferred to, the courthouse will be less than an hours' drive away for either party. (*Id.*, Exs. F & G.) By contrast, this Court's location would involve the parties commuting to a Los Angeles-area airport, flying across the country to Philadelphia, and then driving to Wilmington. In addition to the time and expense of cross-country air travel, trips to this Court will certainly involve at least one night's lodging and meals, probably two.

The final issue to be considered for this factor—the parties' relative financial position—also favors transfer. As mentioned above, HBT has only [redacted] employees. (Hodgson Decl. ¶ 6.) [redacted] (*Id.* ¶ 17.) Abraxis, by contrast, is in a much better financial position. Sales of ABRAXANE®, the branded drug at issue in this case, topped $992 million in 2017 alone. (Gerasimow Decl., Ex. F at 38-39.) Indeed, since its introduction, ABRAXANE® has driven billions of dollars in revenue. The parties' disparate financial position strongly favors transfer, which will greatly ease the financial burden on HBT. That Abraxis can easily afford to litigate in inconvenient forums does not change the fact that the Central District of California would be more convenient, even for Abraxis. This factor strongly favors transfer.

v. The Convenience of Witnesses Strongly Favors the Central

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can no longer be used as a conclusive judicial admission but that it is admissible in evidence at the instance of the adversary as an evidentiary admission."). Indeed, notwithstanding the Amended Complaint, the evidence indicates that Abraxis is headquartered in LA. (Gerasimow Decl., Exs. I & J.)

District of California.

This factor strongly favors transfer. All known witnesses who may testify at trial reside in California. All of HBT's [redacted] employees, including all of the employees who worked on developing HBT's NDA Product and preparing the NDA, work and reside in the Central District of California. (Hodgson Decl. ¶ 6.) Likewise, all four individuals named as inventors on the Patents-in-Suit are listed as residing in California. In fact, three of these individuals are listed as residing in Los Angeles County, in the heart of the Central District of California. (Am. Compl., Exs. A-J & L, D.I. 6-1.) The fourth individual, who is named on only one of the Patents-in-Suit, is listed as residing in San Francisco (*id.*, Ex. K), which is of course much closer to the Central District of California than to Delaware. Critically, none of the named inventors currently work for Plaintiffs, meaning subpoenas will be required to compel their attendance at depositions and trial. (Gerasimow Decl., Exs. K-N.); *Jumara*, 55 F.3d at 879. In addition, the attorney who prosecuted the Patents-in-Suit is located in California. (Gerasimow Decl., Ex. O.) And the individual identified as the inventor of the primary prior art reference cited during prosecution of the original Patent-in-Suit is listed as residing on the West Coast. (*Id.*, Exs. P, Q.)

vi. Books and Records Are Primarily Located in the Central District of California.

All relevant books and records are located in the Los Angeles area, strongly favoring transfer. *See In re Genentech, Inc.*, 566 F.3d 1338, 1345 (Fed. Cir. 2009) ("In patent infringement cases, the bulk of the relevant evidence usually comes from the accused infringer," here, HBT). As mentioned above, HBT developed its NDA Product in Brea, California, and worked to prepare its NDA there. HBT maintains all of its documents and other materials [redacted] at its Brea facilities. (Hodgson Decl. ¶ 11.) Similarly, Abraxis developed

ABRAXANE®, the branded drug at issue, in Los Angeles. At the time, Abraxis was an independent company, and it was acquired by Celgene more than five years after ABRAXANE® was approved by FDA. (Gerasimow Decl., Ex. R.) Even if Celgene were a proper party to this action, its books and records have little relevance as merely an after-the-fact corporate parent.

b. The Public Interest Factors Also Strongly Favor Transfer.

i. A Judgment by the Central District of California Is Equally Enforceable.

"Enforceability of the judgment is not an issue" in patent cases arising under federal law. *See Wacoh*, 845 F. Supp. 2d at 603. This factor is therefore neutral.

ii. Practical Considerations Favor Transfer.

This factor, which assesses "practical considerations that could make the trial easy, expeditious, or inexpensive," favors transfer. *Jumara*, 55 F.3d at 879. As mentioned above, trial in the Central District of California will be easier, quicker, and cheaper for the parties. Moreover, a trial there will likely benefit from live testimony by key witnesses, such as the inventors named on the Patents-in-Suit, whom only a court in the Central District of California may be able to compel. Another practical consideration under this factor is the existence of related lawsuits in this District. *See, e.g.*, *Mitek*, 2012 WL 3777423, at *7; *Papst Licensing GmbH & Co. KG v. Lattice Semiconductor Corp.*, 126 F. Supp. 3d 430, 444 (D. Del. 2015). Here, however, there are no related lawsuits in this District. In fact, the only other recently-pending lawsuit involving the Patents-in-Suit had been the first-filed, mirror-image New Jersey Action against HBT.[5] (C.A. No. 2:18-cv-17304.)

iii. Court Congestion in Delaware Favors Transfer.

This factor favors transfer. This District is by far the top venue for Hatch-Waxman cases.

[5] Two related lawsuits, which were previously resolved, were also venued in the District of New Jersey. (C.A. Nos. 2:16-cv-1925 & 2:16-cv-9074.)

(Gerasimow Decl., Ex. S.) Indeed, from 2016 to 2017 (the year for which most recent data is available), ANDA cases in Delaware surged 60%, to 241 cases. (*Id.*) At present, this District has 936 open patent infringement cases, while the Central District of California has only 242. (Gerasimow Decl., Ex. T.) Further, the District of Delaware has only four District Judges in comparison to the Central District of California's 25+ judges.

iv. The Local Interests Lie In California.

This factor favors transfer. California obviously has a strong interest in cases involving two companies headquartered in California, especially where the development of both the branded and generic products at issue took place in California. In contrast, there is no local interest for Delaware except for the corporate formality of incorporation.

v. California Likewise Has a Public Policy of Protecting Patent Rights.

This factor is typically neutral in the context of patent litigation, as "patent issues do not give rise to a local controversy or implicate local interests," *OpenTV, Inc. v. Netflix, Inc.*, No. 12-1733 (GMS), 2014 WL 1292790, at *4 (D. Del. Mar. 31, 2014).

vi. California Courts Are Just as Familiar with Patent Law.

"This is not a diversity case, and thus knowledge of state law is irrelevant here." *See Wacoh*, 845 F. Supp. 2d at 604. This factor is therefore neutral.

C. <u>The Court Should Dismiss Counts I, IV, VI, VII and IX-XII of the Amended Complaint Because HBT Does Not Seek FDA Approval for the Indications Covered by the Patents Asserted Therein.</u>

Whether or not this action is transferred, the Amended Complaint (D.I. 6) fails to state a claim with respect to patents that only encompass indications for which HBT has not sought FDA approval. Those claims—Counts I, IV, VI, VII and IX-XII—should therefore be dismissed pursuant to Federal Rules of Civil Procedure 12(b)(1) and/or 12(b)(6), as explained below.

1. A Generic Applicant Cannot Infringe a Patent Covering Methods of Use For Which FDA Approval Is Not Sought.

The Hatch-Waxman Act strikes a balance between the competing policy interests of "(1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market." *Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002). A drug manufacturer seeking FDA approval to market the generic form of a previously approved drug for an approved use may submit an Abbreviated NDA, rather than submitting a full NDA. *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1318 (Fed. Cir. 2012); *see also Astrazeneca Pharm. LP, IPR v. Apotex Corp.*, No. 10-388 (RBK/KW), 2010 WL 5376310, at *2 (D. Del. Dec. 22, 2010). Alternatively, as is the case here, a generic manufacturer may submit an NDA of its own but nonetheless rely on the safety and efficacy investigations conducted by the original branded manufacturer. FDCA § 505(b)(2), 21 U.S.C. § 355(b)(2). Such applications are referred to herein as 505(b)(2) NDAs.

To allow for prompt judicial determination of whether a generic applicant's drug or method of using the drug infringes a valid patent, the Act dictates that the filing of an ANDA or 505(b)(2) NDA "for a drug claimed in a patent or the use of which is claimed in a patent" is itself "an act of infringement." 35 U.S.C. § 271(e)(2)(A); *see also Bayer*, 676 F.3d at 1318. The artificial act of infringement created by the generic application filing establishes the court's jurisdiction to decide a branded drug manufacturer's patent infringement action against the generic manufacturer. *Bayer*, 676 F.3d at 1318. The Act further dictates that a branded pharmaceutical manufacturer obtaining FDA approval for a new drug must identify every patent relating to the drug "with respect to which a claim of patent infringement could reasonably be asserted." 21 U.S.C. § 355(b)(1); *see also Bayer*, 676 F.3d at 1318. The FDA identifies these patents in a publication called *Approved Drug Products with Therapeutic Equivalence*

Evaluations, referred to in the industry as the "Orange Book." *Bayer*, 676 F.3d at 1318.

An ANDA or 505(b)(2) NDA applicant is required to consult the Orange Book and take action relating to all pertinent patents. *Id.* Accordingly, if an applicable method-of-use patent exists that is set to expire after the release of the generic drug, the applicant must accompany its application with either a Paragraph IV certification, 21 U.S.C. §§ 355(b)(2)(A)(iv), 355(j)(2)(A)(vii)(IV), a statement indicating that the applicant intends to market the generic drug for a different method of use than those claimed by relevant Orange Book patents, 21 U.S.C. §§ 355(b)(2)(B), 355(j)(2)(A)(viii); *see also Bayer*, 676 F.3d at 1318-19, or both. The Federal Circuit has described such statements as "carve-outs" because they "limit[] the scope of the generic manufacturer's ANDA to approved indications that are not claimed by valid patents listed in the Orange Book." *Astrazeneca*, 2010 WL 5376310, at *2.

The generic applicant may also file a Paragraph IV certification, asserting that the patent "is invalid or will not be infringed by the manufacture, use, or sale" of the generic drug. 21 U.S.C. §§ 355(b)(2)(A)(iv), 355(j)(2)(A)(vii)(IV); *see also Bayer*, 676 F.3d at 1319. In that case, the generic applicant must then send a notice letter to the holder of the original NDA and the patent owner, 21 U.S.C. §§ 355(b)(3), 355(j)(2)(B), receipt of which triggers a 45-day window for the patent holder to file a patent infringement lawsuit. 21 U.S.C. §§ 355(c)(3)(C), 355(j)(5)(B)(iii); *see also Astrazeneca*, 2010 WL 5376310, at *3. Upon commencement of the lawsuit, a 30-month stay of approval of the ANDA or 505(b)(2) application is put in place, running from the date of the patentee's receipt of the notice letter. 21 U.S.C. §§ 355(c)(3)(C), 355(j)(5)(B)(iii); *see also Astrazeneca*, 2010 WL 5376310, at *3.

For a method-of-use patent, this "artificial" infringement claim lies only against a patented use that has been approved by the FDA. *Bayer*, 676 F.3d at 1319. A generic applicant

may not seek approval for an unapproved or off-label use of a drug; thus, it necessarily follows that no claim is stated under 35 U.S.C. § 271(a)-(c) or 35 U.S.C. § 271(e)(2)(A) with respect to a patent claiming only an excluded use. *Bayer*, 676 F.3d at 1319.

2. The '891, '375, '348, '156, '543, '318, '046, and '409 Patents Cover Methods of Treating Pancreatic and/or Lung Cancer.

In *Bayer*, the Federal Circuit established that a district court may enter judgment on the pleadings where it is clear from the pleadings that the use of the drug for which the generic filer is seeking FDA approval is not covered by the asserted patents. *Bayer*, 676 F.3d at 1326. Here, it is clear that the following Patents-in-Suit cover only methods of using ABRAXANE® to treat particular cancers (collectively, the "Treatment Patents-in-Suit"), *i.e.*, pancreatic or lung cancer:

Count	Am. Compl.	Patent	Title of Patent	Claimed Use
I	¶¶ 28-36; Ex. A	7,758,891	"Combinations and modes of administration of therapeutic agents and combination therapy"	"A method of treating pancreatic cancer" (claim 1)
IV	¶¶ 55-63; Ex. D	8,034,375	Same as above	"A method of treating non-small cell lung cancer" (claim 1)
VI	¶¶ 73-81; Ex. F	8,268,348	Same as above	"A method of treating non-small cell lung cancer" (claims 1 & 36)
VII	¶¶ 82-90; Ex. G	8,314,156	"Compositions and methods of delivery of pharma-cological agents"	"A method of treating lung cancer" (claim 1) "A method of treating pancreatic cancer" (claim 13)
IX	¶¶ 100-108; Ex. I	9,101,543	"Combinations and modes of administration of therapeutic agents and combination therapy"	"A method of treating pancreatic cancer" (claim 1)
X	¶¶ 109-117; Ex. J	9,393,318	"Methods of treating cancer"	"A method of treating NSCLC [non-small cell lung cancer]" (claim 1)
XI	¶¶ 118-126; Ex. K	9,511,046	"Methods of treating pancreatic cancer"	"A method for treating metastatic or locally advanced pancreatic cancer"
XII	¶¶ 127-135; Ex. L	9,597,409	"Methods of treating cancer"	"A method of treating NSCLC [non-small cell lung cancer]" (claim 1)

The chart above identifies the method of use claimed in each independent claim of the Treatment Patents-in-Suit. The remaining claims of the Treatment Patents-in-Suit are all dependent on the independent claims identified above and thus incorporate by reference all of the limitations of the

independent claim(s), including the claimed methods of use. 35 U.S.C. ¶ 4; *see also Jeneric/Pentron, Inc. v. Dillon Co.*, 205 F.3d 1377, 1383 (Fed. Cir. 2000); *Robotic Vision Sys., Inc. v. View Eng'g, Inc.*, 189 F.3d 1370, 1376 (Fed. Cir. 1999). Accordingly, all claims of the Treatment Patents-in-Suit, whether independent or dependent, are directed to methods of treating particular cancers, namely pancreatic cancer (the '891, '156 (claim 13), '543, and '046 patents) or lung cancer (the '375, '348, '156 (claim 1), '318, and '409 patents).

3. HBT Stated to FDA that it is Not Seeking Approval for the Treatment of Pancreatic or Lung Cancer.

HBT's NDA, by contrast, does ***not*** seek FDA approval of its NDA Product for the indications covered by the Treatment Patents-in-Suit. Specifically, HBT's NDA includes a "Method of Use Certification Statement" pursuant to Section 505(b)(2)(B) of the FDCA, 21 U.S.C. § 355(b)(2)(B), that HBT is not seeking approval for the treatment of pancreatic or lung cancer. Specifically, HBT stated as follows:

(*See* Gerasimow Decl., Ex. U.) In short, HBT stated to FDA that it is ***not*** seeking approval for the treatment of pancreatic or lung cancer.[6]

4. The Court Should Dismiss All Counts Alleging Infringement of the Treatment Patents-in-Suit.

The Court should dismiss Counts I, IV, VI, VII and IX-XII—each of which alleges

[6] This Court may consider HBT's method of use statement on a Rule 12(b)(6) motion to dismiss, as Plaintiffs reference HBT's NDA, which contains such statement, in the Amended Complaint (*see, e.g.*, D.I. 6 ¶ 25). *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997). HBT's method of use statement is also described in its notice letter, also referenced in the Amended Complaint (*see, e.g.*, D.I. 6 ¶ 27).

infringement of the Treatment Patents-in-Suit—because HBT is not seeking FDA approval for the methods of use covered by such patents. *Bayer*, 676 F.3d at 1319. For each of the Treatment Patents-in-Suit, Plaintiffs allege various types of infringement by HBT. In particular, Plaintiffs allege that: (1) HBT's submission of its NDA constituted an artificial act of infringement under 35 U.S.C. § 271(e)(2) (*see, e.g.*, Am. Compl., D.I. 6 ¶ 29); (2) upon FDA approval, HBT will commit direct infringement under 35 U.S.C. § 271(a) (*see, e.g.*, Am. Compl., D.I. 6 ¶ 31); (3) upon FDA approval, HBT will induce infringement by others under 35 U.S.C. § 271(b) (*see, e.g.*, Am. Compl., D.I. 6 ¶ 32); and (4) upon FDA approval, HBT will contribute to the infringement of others under 35 U.S.C. § 271(c) (*see, e.g.*, Am. Compl., D.I. 6 ¶ 33). However, HBT cannot be found liable for any alleged infringement as to off-label uses of its NDA Product.

Regarding alleged infringement under Section 271(e)(2), the Federal Circuit has held that "because an ANDA may not seek approval for an unapproved or off-label use of a drug under 21 U.S.C. § 355(j)(2)(A)(i), it necessarily follows that 35 U.S.C. § 271(e)(2)(A) does not apply to a use patent claiming only such a use." *Bayer*, 676 F.3d at 1319 (quoting *Warner-Lambert*, 316 F.3d at 1356). Here, the case for dismissal is clear. The Treatment Patents-in-Suit cover methods of treating pancreatic and lung cancer; HBT, however, is not seeking approval for the treatment of those cancers. There can be no infringement under Section 271(e)(2). *Id.*

Regarding Sections 271(a), the Federal Circuit has held that, for a method claim, a "[d]irect infringement under § 271(a) occurs where all steps of a claimed method are performed by or attributable to a single entity." *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020, 1022 (Fed. Cir. 2015). Here, Plaintiffs cannot plausibly allege that HBT will, upon approval, practice any of the methods of use covered by the Treatment Patents-in-Suit. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 564 (2007) ("look[ing] for plausibility in this complaint").

As a drug manufacturer, HBT may make its NDA Product upon FDA approval. However, HBT will not treat patients and, without performing the methods of use covered by the Treatment Patents-in-Suit, cannot directly infringe those patents. *Akamai*, 797 F.3d at 1022.

Regarding alleged indirect infringement under Sections 271(b) and (c), the Federal Circuit has held that, "where a product has substantial noninfringing uses, intent to induce infringement cannot be inferred even when the defendant has actual knowledge that some users of its product may be infringing the patent." *Warner-Lambert*, 316 F.3d at 1365; *see also Bayer*, 676 F.3d at 1321 ("[T]he defendants' conduct would constitute … inducement of infringement under section 271(b) … only if the defendants' ANDAs sought approval for the use protected by the [asserted patent]."). Here, HBT's NDA explicitly states [redacted] (Gerasimow Decl., Ex. V.) In other words, HBT cannot induce others to infringe because its proposed labelling (*id.*, Ex. R) lacks instructions directing physicians and other medical professionals to use its NDA Product in ways covered by the Treatment Patents-in-Suit. As the Federal Circuit has explained, HBT's "request to make and sell a drug labeled with a permissible (non-infringing) use cannot reasonably be interpreted as an act of infringement (induced or otherwise) with respect to a patent on an unapproved use, as the ANDA does not induce anyone to perform the unapproved acts required to infringe." *Warner-Lambert*, 316 F.3d at 1364-65.

IV. CONCLUSION

For at least the foregoing reasons, HBT respectfully requests that the Court dismiss Plaintiff Celgene, transfer this action to the Central District of California, and dismiss Counts I, IV, VI, VII, and IX-XII of the Amended Complaint (D.I. 6).

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